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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/600,881 | 06/20/2003 | John S. Brandstetter | P-10169.00 | 6677 |

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| EXAMINER | |
|---|---|
| KRAMER, NICOLE R | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3762 | |

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/600,881 | BRANDSTETTER ET AL. | |
| | Examiner | Art Unit | |
| | Nicole R. Kramer | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,944,744 ("Paul et al.") in view of U.S. Patent No. 6,275,734 ("McClure et al.").

Paul et al. teaches that it is well known in the art for an implantable cardiac stimulator to store information regarding the amplitude of cardiac signals in memory incorporated within the device (see col. 3, lines 48-60). The stored amplitude information may be transmitted to an external programmer so that the physician can analyze the data and reprogram the implanted device's sense circuit to a suitable sensing threshold (see col. 3, lines 48-60). It is important to reprogram the sensing threshold periodically, because changes in the amplitude of the electrical signals are common in the same patient due to a variety of factors, including changes in the electrophysiology of the heart (see col. 3, lines 30-36). Paul et al. further teaches that such changes in the electrophysiology of the heart are most drastic during an episode of tachyarrhythmia, which are accompanied by a relatively rapid and sustained change in the amplitude of cardiac electrical events (see col. 3, lines 35-40). However, Paul et al.

fails to specifically disclose that the stored amplitudes (which are later transmitted to the external programmer for review by the physician) are measured upon pre-detection or detection of a tachyarrhythmia episode. McClure et al. teaches an ICD that stores an IEGM signal in response to detection of a particular cardiac event (see Abstract; see also col. 2, lines 15-34; see also col. 6, lines 38-57; see also col. 8, lines 30-67). McClure et al. teaches that preferably the processor records only a predetermined portion of the IEGM signal and the resulting therapy to allow a treating physician to review the heart function and the device function during the episode (see col. 8, lines 30-40). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method disclosed in Paul et al. such that the stored amplitudes are measured upon detection of a particular cardiac event as taught by McClure et al. in order to allow a treating physician to review the heart function and the device function during the episode. Further, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention that the particular cardiac event (which initiates such amplitude measurements) be a tachyarrhythmia event, since Paul et al. teaches that changes in the electrophysiology of the heart are most drastic during an episode of tachyarrhythmia, which are accompanied by a relatively rapid and sustained change in the amplitude of cardiac electrical events (see col. 3, lines 35-40).

With respect to the claim limitation of claims 1 and 13 relating to "pre-detection criteria associated with the potential detection of a tachyarrhythmia episode" (rather than claims 7 and 19 relating to "detection criteria associated with a tachyarrhythmia episode"), low level signals are indicative of a potential tachyarrhythmia as well as an

occurring tachyarrhythmia (see, for example, U.S. Patent No. 5,117,824 to Keimel et al. at col. 2, lines 20-32. See also U.S. Patent No. 5,339,820 to Henry et al. at col. 4, lines 30-34 & 56-60 and col. 6, lines 39-43). Accordingly, Examiner considers detection of such criteria to necessarily satisfy the claimed "pre-detection criteria" as well as the claimed "detection criteria."

With respect to claims 2, 6, 8, 12, 14, 18, 20, and 24, it is well known that cardiac signals have diminished peak amplitudes during tachyarrhythmia episodes such as tachycardia or fibrillation (see, for example, U.S. Patent No. 5,117,824 to Keimel et al. at col. 2, lines 20-32. See also U.S. Patent No. 5,339,820 to Henry et al. at col. 4, lines 30-34 & 56-60 and col. 6, lines 39-43). Detection of such low-level signals is important for purposes of initiating tachyarrhythmia and/or defibrillation therapies (see, for example, U.S. Patent No. 5,117,824 to Keimel et al. at col. 2, lines 5-10). Accordingly, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention for the physician to adjust the sensing threshold to a level that assures sensing of such low-level signals in order to ensure that the pacemaker properly detects such events for purposes of initiating tachyarrhythmia and/or defibrillation therapies.

With respect to claims 3-4, 9-10, 15-16, and 21-22, McClure et al. teaches that the IMD delivers the appropriate therapy upon detection of a tachyarrhythmia episode (see col. 6, lines 38-45). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method disclosed in Paul et al. such that the IMD delivers the appropriate therapy upon detection of a tachyarrhythmia

episode as taught by McClure et al. in order to terminate the tachyarrhythmia episode and provide effective treatment for the patient.

With respect to claims 5, 11, 17, and 23, Paul et al. discloses that most pacemaker sense circuits incorporate or are coupled to a comparator circuit which compares the magnitude of the amplified sense signal to a reference signal in order to determine that a physiologically significant event has occurred (see col. 3, lines 11-25 of Paul et al.). Such sense event signals are necessarily processed, as described in McClure et al, in order to detect a tachyarrhythmia episode (see col. 6, lines 25-45 of McClure et al.)

***Response to Arguments***

3. Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRK
6/23/06

George Manuel
Primary Examiner